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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/944,175

09/04/2001

Nobuhiko Ogura

Q65952

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10/16/2006

SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, N.W.
Washington, DC 20037-3202

EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/944,175

Applicant(s)

OGURA, NOBUHIKO

Examiner

MY-CHAU T. TRAN

Art Unit

1639

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: NONE.
Claim(s) objected to: NONE.
Claim(s) rejected: 1,2,4-8 and 10-22.
Claim(s) withdrawn from consideration: NONE.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Attached Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.


MARK SHIBUYA, PH.D.
PATENT EXAMINER

ADVISORY ACTION (CONT.)

1. The amendment filed 08/10/2006 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because:

- a. The proposed claim amendment required further considerations and/or search (e.g. the new limitation of “*combined body of the probe, the captured target, and the substance derived from a living organism other than the target*” of claims 1, 4-7, and 15, and “*wherein during the fractionating, the combined body of the probe and the captured target and the substance derived from a living organism other than the target is separated into a plurality of fractions based on molecular weight*” of claim 1).
- b. The proposed claim amendments raise the issue of new matter, e.g. the new limitation of “*combined body of the probe, the captured target, and the substance derived from a living organism other than the target*” of claims 1, 4-7, and 15 raise the issue of new matter wherein the structural feature of the claimed “*combined body*” include an additional structure, i.e. “*the substance derived from a living organism other than the target*”, and as a result this amendment render the claims narrower than the original disclosure. Moreover, applicant did not provide any indication where such support exists for the new limitation.
- c. The proposed claim amendment may necessitate the modification of outstanding rejection(s) to address the new limitation, e.g. “*combined body of the probe, the captured target, and the substance derived from a living organism other than the target*” of claims 1, 4-7, and 15.

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- d. The proposed claim amendment may necessitate the raising of new prior art rejections and/or 112 issues.
- e. There is no convincing showing under 37 CFR 1.116(b) why the proposed claim amendment was not earlier presented.
- f. Applicant arguments are moot in view of the non-entry of the proposed claim amendment. However, the following points are addressed for completeness.
- g. With respect to enablement, the examiner maintains that the practice of the full scope of the invention would require undue experimentation, especially the combine method steps of (a) fixing the probes on a substrate wherein the type of attachment is "covalent attachment" of the probe onto the substrate, and (b) fractionating combined bodies of the probe and capture target, i.e. the complex of both the probe and capture target are "separated" from the substrate. Applicant provide no working examples for this method and the scope of the method as claimed include the steps of "covalent attachment" of the probe onto the substrate *and* the migration of the complex of probe and target, i.e. fractionating, which has yet to be identified by the specification and the state of the art. Thus, the specification, at the time the application was filed, does not satisfy the enablement requirement for the claimed method that include the steps of a) fixing the probes on a substrate, i.e. "covalent attachment" of the probe onto the substrate, and b) fractionating combined bodies of the probe and capture target, i.e. the complex of both the probe and capture target are "separated" from the substrate. Moreover, applicant's argument address the enablement regarding only the method step of fixing the probes on a substrate wherein the type of attachment is "covalent

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attachment” of the probe onto the substrate. *However*, the enablement rejection is in regard to the combine method steps of (a) fixing the probes on a substrate wherein the type of attachment is “covalent attachment” of the probe onto the substrate, and (b) fractionating combined bodies of the probe and capture target, i.e. the complex of both the probe and capture target are “separated” from the substrate. Consequently, applicant argument is confusing.

h. With respect to the 102(b) rejection based on Ishii et al., applicant alleges that Ishii et al. does not disclose the step of “*fractionating the target*”. The examiner respectfully disagrees since Ishii et al. does disclose the step of “*fractionating*”, i.e. fractionating the combined bodies of the probe and the target (see e.g. pg. 3550, left col., line 31 thru right col., line 5; pg. 3551, fig. 1(b) showing the electromobility shift assay (i.e. fractionating step); pg. 3551, fig. 2(b) showing supershift of mAb/Rbflp complex). Moreover, the claimed method recite fractionating the combine bodies of the probe *and* target, i.e. the claimed method recite does not recite fractionating *only* the target. Thus, applicant is arguing limitation not recited in the claims.

i. For all the reasons above the proposed claim amendment does not place the case in better condition for allowance and/or appeal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810.

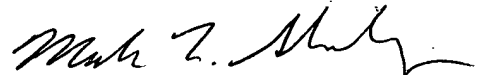
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The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00;
Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
October 11, 2006


MARK SHIBUYA, PH.D.
PATENT EXAMINER